As stated in the USPTO's own "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement,":

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicants was in possession of the claimed invention.

(see, Federal Register, Vol. 66, No. 4, p. 1099-1111, January 5, 2001). In accordance with these standards, Applicants have indeed, provided a sufficient written description of the claimed invention.

The Office Action asserts that the phrase "nucleic acid of interest, associated with a genetic trait, condition or abnormality **not present** in the pregnant female" is unsupported by Applicants' specification (emphasis in the original -- see, page 3 of the Office Action). The Office Action further asserts that the specification does not support the concepts of either nucleic acids that differ between maternal genome and fetal genome and spontaneous differences.

The specification does, in fact, provide support for the concept of the recited terminology. By way of illustration, Applicants' definition of "prenatal diagnosis" in the "Summary and Objects of the Invention" section extends to "fetal abnormalities which may be for example chromosomal aneuploidies or simple mutations" (see, paragraph 0009 of the patent application publication). This broad definition in paragraph 9 nowhere limits the "prenatal diagnosis" of this invention to detection of "paternally-derived" traits. Further, this definition nowhere limits the abnormalities to appearing in both the fetus and the pregnant woman. Thus, regarding abnormalities, it is more likely than not that the pregnant female would not have the same abnormality as the fetus. Thus, Applicants' specification clearly contemplates a "nucleic

acid of interest, associated with a genetic trait, condition or abnormality **not present** in the pregnant female."

In addition, in Example 2 (paragraphs 0045-0074 of the published patent application), Applicants describe the quantitative analysis of fetal DNA in maternal serum in aneuploidal pregnancies. The results and data in this example, shown graphically in Figure 1, demonstrate that the concentration of fetal DNA is significantly higher in women with aneuploidal pregnancies as compared with normal pregnancies. **The aneuploidal abnormality was not present in the pregnant women studied.** The abnormality, i.e., a chromosomal aneuploidy -- an abnormality that manifests itself in the fetus as a missing or extra chromosome, was present in the fetuses but not in the pregnant females carrying such fetuses. The nucleic acid of interest used in Example 2 was fetal SRY DNA concentration, since the chromosomal aneuploidy manifests itself in higher than "normal" concentrations of fetal DNA, as is shown by the data in Figure 1. In this case, the SRY DNA served as the "nucleic acid of interest", since its abnormal concentration is "associated with the genetic trait of, condition or abnormality not present in the pregnant female". Consequently, the present specification does indeed disclose and discuss genetic traits, conditions or abnormalities that are not present in the pregnant female herself.

In addition, Applicants' specification nowhere limits its inventive prenatal diagnostic method to paternally-derived fetal traits. The specification does acknowledge that the fetal DNA detection method of this invention would be "most useful" for paternally-inherited sequences which are not possessed by the mother. The specification, however, nowhere explicitly or implicitly limits the inventive method to these situations.

For these reasons, the claim language "nucleic acid of interest, associated with a genetic trait, condition or abnormality not present in the pregnant female" is described and discussed in the specification and does not constitute new matter.

The Office Action also asserts that claims 38, 40, 41, and 45 lack written description support for a "comparison between maternal genome while carrying the fetus and free of contamination by fetal nucleic acids." (See, page 4 of the Office Action). Applicants direct the Examiner's attention to Example 3 in their specification, which concerns the prenatal determination of fetal RhD status. In this Example, genomic DNA was isolated from the buffy

coat (white blood cells) isolated during recovery of the plasma sample from the pregnant females to confirm by genotyping that the pregnant females were RhD negative (Paragraphs 0097 and 0085, 0087 of the patent application publication). Thus, a comparison between the maternal plasma and counterpart "maternal nucleic acid sample from the pregnant female free of contamination by fetal nucleic acids" was, in fact, carried out in Example 3.

Further, additional support for the comparisons recited in claims 38, 40-41 and 45 can be found in Example 5, which is directed to quantitative analysis of fetal DNA in maternal plasma and serum. In this Example, a number of pregnant females involved in the study were recruited from an *in vitro* fertilization (IVF) program, and maternal blood samples were obtained from these females prior to conception as well as afterwards (paragraphs 0132, 0152 of the patent application publication). These IVF females were confirmed to be negative for SRY sequences in their sera prior to conception, and these preconception data points are noted at a zero gestation age in the results shown in Figures 4A-4L.

The Office Action also asserts that claim 46 lacks written description support for an "assay requiring two probes, one to an aneuploidy sequence and one to a non-aneuploidy sequence." (See, page 4 of the Office Action. Applicants direct the Examiner's attention to the "second method" (discussed in paragraph 0020 of the patent application publication) in which the prenatal diagnostic method of this invention may be applied to chromosomal aneuploidies. The method described in paragraph 0020 "involves the quantitation of fetal DNA markers on different chromosomes" and notes that the "absolute quantity of fetal chromosomal 21-derived DNA [which is associated with Down's syndrome] will always be greater that that from the other chromosomes". The reference to "fetal DNA markers" and "**other** chromosomes" (emphasis added) makes it clear that separate, different probes would be required for identification of the respective chromosomal marker nucleic acids of interest. The subject matter of claim 46 is consequently supported by Applicants' specification. The Office Action erroneously asserts that because paragraph 0020 of the patent application publication "is directed to PCR techniques" and PCR does not require probes, Applicants arguments are not persuasive. The Examiner has misconstrued paragraph 0020 of the patent application publication, which states, in whole:

> A second method involves the **quantitation** of fetal DNA markers on different chromosomes. For example, for a fetus affected by Down's

> Syndrome the absolute **quantity** of fetal chromosomal 21-derived DNA will always be greater than that from the other chromosomes. The recent development of very accurate **quantitative PCR techniques**, such as real time **quantitative PCR** (Heid et al 1996) facilitates this type of analysis. (emphasis added)

Thus, regardless of whether PCR does or does not require probes, paragraph 0020 of the patent application publication teaches quantifying fetal DNA markers, which most commonly employs probes. Indeed, in a technique such as quantitative PCR in which oligonucleotides are used to detect the presence of as well as quantify the amount of a particular nucleic acid molecule (such as fetal chromosomal 21-derived DNA), the oligonucleotides used serve as, in fact, probes. A primer and probe are both nucleic acid molecules; the primer traditionally used for amplification and the probe used for detection and quantification. The primers understood by the Examiner to be used in PCR actually function as "probes" when the nucleic acid is being detected and quantified.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, as allegedly failing to provide sufficient written description be withdrawn.

II. The Claimed Invention Is Sufficiently Enabled

Claims 37-48 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to provide an enabling disclosure. The Office Action asserts that although methods of detecting paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female are enabled, methods of performing the same procedure to detect a nucleic acid that is associated with a genetic trait, condition or abnormality not present in the pregnant female are not enabled. The Office Action mistakenly concludes that it would require undue experimentation to determine whether the detected nucleic acid was a result of the maternal DNA found in the maternal plasma or serum or whether the detected nucleic acid was from the fetus. Applicants traverse the rejection and respectfully request reconsideration because one skilled in the art would be able to practice the claimed invention without being required to perform undue experimentation.

As will be recognized, the enablement requirement of §112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (the legal standard for enablement under §112 is whether one skilled in the art would be able to practice the invention without undue experimentation). In this respect, the following statement from *In re Marzocchi*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971), is noteworthy:

> The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.
>
> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented **must** be taken as in compliance with the enabling requirements of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support. (emphasis added)

Any assertion by the Patent Office that an enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974).

The thrust of the reasoning for the enablement rejection set forth in the Office Action appears to be based upon a misconception of the claim language. The Office Action asserts that a "pregnant female may be a carrier or [sic] a nucleic acid associated with a genetic trait" such as diabetes, hair color, or schizophrenia in which two copies of the gene are necessary for phenotypic expression. If such a pregnant female possesses only one copy of the gene in her genome, although she will not demonstrate the phenotypic expression, she has the potential to possess the nucleic acid molecule in her plasma or serum. Thus, a nucleic acid molecule that is detected in the maternal plasma or serum in such a pregnant female cannot for certain be

identified as being of fetal origin. Applicants' claims 37-40, however, do not encompass this situation. Claim 37, for example, recites that the "genetic trait" is not present in the pregnant female. Indeed, the Office Action has already stated that a pregnant female may be a carrier of a nucleic acid associated with a genetic trait (i.e., she has a single copy of a recessive gene). If the female is a carrier of a gene associated with a genetic trait, then the nucleic acid associated with the genetic trait is **present** in the pregnant female. Such a pregnant female is explicitly excluded from claims 37-40 (i.e., "not present" in the pregnant female).

In those claims directed to aneuploidy, although the pregnant female may contain one copy of a gene or chromosome for that matter, the corresponding fetal DNA is present in an amount that is different that that of the pregnant female. That is, the fetal DNA may have a different copy number (i.e., may have one or more extra copies of chromosomes or one or more less copies of a chromosome).

Applicants' specification nowhere limits its inventive prenatal diagnostic method to paternally-derived fetal traits. Indeed, Applicants' definition of "prenatal diagnosis" recited in the "Summary and Objects of the Invention" section extends to "fetal abnormalities which may be for example chromosomal aneuploidies or simple mutations." (See, paragraph 0009 of the patent application publication) Further, although the claimed invention is acknowledged by Applicants to be "most useful" for paternally-inherited sequences which are not possessed by the mother, one of ordinary skill in the art would appreciate that the claimed methods can be practiced for the detection of prenatal genetic traits, conditions or abnormalities not present in the mother (i.e., mutations that are neither paternally nor maternally derived) using the methodology described in the application.

One skilled in the art, for example, would understand that the absence of the mutation in the maternal genome is determined by comparison of a maternal nucleic acid sample from the female free of contamination by fetal nucleic acids. This could be accomplished through a variety of routine procedures well known in the art (e.g., by comparison with a blood sample obtained prior to pregnancy or by comparison with a tissue sample from the pregnant female). Indeed, "pre-conception" sampling is described in Applicants' specification (see, paragraphs 0152 and 0157 of the published application).

The Office Action attempts to support its assertions of non-enablement by referring to three references (each of which, however, was published after Applicants' filing date). Significantly, none of the references teaches or even suggest that Applicants' claimed invention will not work. Indeed, the references do not purport to be reviews of Applicants' claimed invention and are, therefore, irrelevant to the issue of enablement of Applicants' claimed invention.

For example, Amicucci et al., Clin. Chem., 2002, 46, 301-302 is a brief report on a single patient (see end of first paragraph) that concluded (see last paragraph) that the autosomal dominant disorder myotonic dystrophy could possibly be diagnosed in the fetus via sampling of the maternal plasma. The authors' statement that their "test seems appropriate only for monitoring paternally expanded alleles [of myotonic dystrophy]" cannot with any fairness be extrapolated to Applicants' claimed invention. Indeed, Applicants' published patent application is not referenced in this brief article.

Lo (one of the named inventors of the present application), Ann. Med., 1999, 31, 308-312 describes his work in diagnosing fetal rhesus D status by analysis of maternal plasma or serum DNA. The review does not include any discussion of experimental work other than prenatal diagnosis of fetal RhD genotyping. The statement by the author under "Future Directions" on page 310 regarding the possibility of extending the RhD methodology to other single-gene disorders, merely acknowledges the broad application of the approach not only to detection of paternally inherited genes, but also DNA polymorphisms or mutations that are distinguishable from the maternally inherited counterparts. Thus, the Lo reference is irrelevant to the issue of enablement of Applicants' claimed invention.

Pertl et al., Obstetrics & Gynecology, 2001, 98, 483-490 is merely a review of 369 MedLine-searched articles published between January 1970 and March 2000 which mention "fetal DNA", "plasma" and "serum". Although some of the MedLine articles mentioned include inventor Lo as an author, the focus of this article is a broad view of prenatal diagnosis up until the March 2000 publication cut-off and the authors' conclusions are based on this perspective. The review article adds no substantive information to the issue of enablement of Applicants'

claimed invention, particularly since Applicants' US application had not yet been published and since their counterpart international application is not cited.

Thus, none of the three cited references provides any convincing reasons that suggest that Applicants' claimed invention, as defined by pending claims 36-47, is not enabled by the originally-filed specification.

In view of the foregoing, Applicants' claimed methods are clearly enabled by their specification. Thus, there is no reason to believe that one skilled in the art would be required to perform any amount of undue experimentation in order to make and use the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

III. Obviousness-Type Double Patenting

A. U.S. Patent No. 6,664,056

Claims 37 and 39 are rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 6, and 7 of U.S. Patent No. 6,664,056 (hereinafter, the "Lo patent"). Applicants traverse this rejection and respectfully request reconsideration because the Office Action has misapplied the one-way test when the two-way test should have been applied.

In an obviousness-type double patenting rejection, the Examiner must decide whether to impose the one-way test or the two-way test. In the present rejection, the Examiner erroneously imposed the one-way test. The two-way test applies when: a) the patent was the later filed application (i.e., the application at issue is the earlier filed application); b) applicant could not have filed the conflicting claims in a single (i.e., earlier filed) application; and c) there is administrative delay by the PTO causing delay in the prosecution of this earlier filed application. As discussed below, all three prongs of the two-way test are satisfied in the present application. Thus, the two-way test should have been imposed. Further, when the claims are analyzed under the two-way test, an obviousness-type double patenting rejection is not warranted.

Regarding the first prong of the three-way test, the present application, as well as its priority applications, was filed prior to the Lo patent. Indeed, the GB priority application for the

present application was filed March 4, 1997, the PCT application was filed March 4, 1998, and the U.S. nonprovisional application was filed November 29, 1999 -- all clearly before the Lo patent provisional application was filed on October 10, 2000. Moreover, the present continuation application was filed June 1, 2001, five days before the Lo patent nonprovisional application was filed. Therefore, the first prong of the two-way test is satisfied.

Regarding the second prong of the two-way test, the present application could not have been filed with the conflicting claims (i.e., claims 1-4, 6, and 7 of the Lo patent) in a single application because at the time of filing the applications of the present invention's family, the assignee of the present application was not in possession of the particular species claimed in the Lo patent. Although the present application discloses use of the method for sex determination, it does not explicitly disclose sex determination by use of "mRNA transcribed from the ZFY gene," as claimed by the Lo patent. Further, the Lo patent claims were filed after the present application was filed and when Lo was no longer employed by the assignee of the present application. In other words, the assignee of the present application could not claim that which it did not specifically possess at the time of filing either because it was not invented yet or because Lo was no longer an employee. Thus, the second prong of the two-way test is satisfied.

The third prong of the two-way test involves an analysis of whether the PTO or the applicant is primarily responsible for the delay in prosecution, thus resulting in the issuance of the later-filed application (i.e., the issuance of the Lo patent). Courts have considered reasons for the delay in evaluating the appropriateness of a double patenting rejection. M.P.E.P. §804.II.B.1.b. None of the reasons previously considered by the courts in the cases described below are applicable in the present application.

For example, the Third Circuit held that a voluntary election to postpone acquisition of the broader patent after the issuance of the later filed narrower application is not a case of administrative delay. *Pierce v. Allen B. DuMont Labs., Inc.*, 297 F.2d 323, 131 U.S.P.Q. 340 (3d. Cir. 1961). In *Pierce*, the patentee "voluntarily delayed the issuance of a patent on his generic claim because of his desire to have an interference declared with a rival inventor" and whereby the generic claim issued seven years after narrower claims. *Pierce* at 343. In the present case,

although Applicants have requested extensions of time, Applicants have not voluntarily chosen to postpone prosecution "dictated by [its] own judgment of economic advantage." *Pierce* at 345.

The Federal Circuit in *In re Emert* has held that the one-way test is applicable when the applicant, rather than the PTO, significantly controls the rate of prosecution of the application at issue. 124 F.3d 1458, 44 U.S.P.Q.2d 1149, 1152 (Fed. Cir. 1997). Applicant Emert received "numerous" time extensions. *Id.* In *Emert*, after the initial obviousness rejection, the applicant waited six months and twice filed, after twice abandoning, a substantially similar continuation application. The applicant did not make a substantive response to the PTO for more than two years after the original rejection. In the meantime, the improvement patent issued. Thus, the Emert Court found that during the critical three-year co-pendent period of the applications, the applicant was responsible for the delays in prosecution. In the present case, it is not appropriate to find any delay in prosecution due to the applicant under the Emert Court's assessment. Applicant has requested four extensions of time, with three of them occurring during the copendent period of the Lo patent and the present invention. Three extensions of time are not "numerous" time extensions, but only a few. Further, although these extensions provided for the maximum period to reply, Applicants, unlike *Emert*, substantively responded to the PTO within 6 months of the original rejection. In fact, during the two years following the original rejection, Applicants substantively responded twice and engaged the PTO Examiner in an interview. Moreover, although the present invention is a continuation application, unlike the Emert application, it was not filed after abandoning earlier applications. Clearly, Applicants were fully active in prosecuting the present application and did not "substantially control" the rate of prosecution.

Courts have recognized that PTO administrative delay justifies the application of the two-way test. The prosecution of the application must not have been held up by the applicant, but rather the delay must have been "over which the applicant does not have complete control." *In re Braat*, 937 F.2d 589, 593, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991). Even if Applicants had taken no extensions of time, the Lo Patent would have still issued before the present application. Indeed, even discounting the full ten months of extensions taken by Applicants from the reply date of the latest Office Action (November 25, 2004), finds the Lo patent issuing before the discounted

progress date. The Lo patent issued on December 16, 2003, while the discounted progress date would place prosecution of the present application at January 25, 2003. Further, the predecessor court of the Federal Circuit noted that but for the rejections of the Examiner that had been reversed by the Patent Office Board of Appeals and the double patenting rejection then before it, a patent on the application at issue could have granted within a few months of the patent used as the basis for the double patenting rejection. *In re Borah*, 354 F.2d 1009, 148 U.S.P.Q. 213, 219 (C.C.P.A. 1966). Therefore, the rejections received with the present application may be seen as delaying prosecution by the PTO, especially, since the arguments have not significantly advanced. Though it would be helpful that the rejections were similarly reversed by the Board, arguably the rejections have impacted the progress of prosecution, and thus, there is not an absence of PTO delay. Applicants have not intentionally or inexcusably delayed prosecution; moreover, the rejections received during prosecution have caused the administrative delay. Therefore, the two-way test is applicable to the present application.

To apply the two-way test in an obviousness-type double patenting rejection, the *Graham* obviousness analysis is applied twice – once with the application claims as the claims in issue and once with the patent claims as the claims in issue. M.P.E.P. §804.II.B.1.b. In a two-way determination, an obviousness-type double patenting rejection is appropriate **only** when **each** analysis forces the conclusion that the invention defined by the claims in issue is an obvious variation of the invention defined by a claim in the other application/patent. *Id.*

An obviousness-type double patenting rejection is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. §103. *In re Braithwaite*, 154 U.S.P.Q. 29, 34 (C.C.P.A. 1967) and *In re Longi*, 225 U.S.P.Q. 645, 648 n.4 (Fed. Cir. 1985). Thus, under the law, the pivotal question in an obviousness-type double patenting analysis is: Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent? *In re Vogel*, 164 U.S.P.Q. 619 (C.C.P.A. 1970). If the answer to this question is no, there can be no double patenting. In making this analysis, then, the proper inquiry is as taught in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). See, M.P.E.P. §804.

One-half of the obviousness analysis involves determining whether the claimed invention of the Lo patent (i.e., claims 1-4, 6, and 7) is an obvious variant of the pending claims

of the present application (i.e., claims 37 and 39). Upon carrying out such an analysis, it is quite clear the claims of the Lo patent are not an obvious variant of the claims of the present application. The difference between the claims is that the Lo patent claim 1 recites a specific fetal trait (i.e., sex of the fetus) by using a specific genetic material (i.e., mRNA from the ZFY gene). In addition, each dependent Lo patent claim in issue possesses one additional limitation. The Office Action has not established that the particular fetal trait (i.e., sex of the fetus) and the particular genetic material (i.e., mRNA from the ZFY gene) recited in the Lo patent claims are an obvious variant of Applicants' claimed invention embodied in claims 37 and 39. Indeed, Applicants' claimed "genus" does not anticipate the "species" claimed in the Lo patent. In addition, Applicants' claimed "genus" does not render obvious the "species" claimed in the Lo patent. Thus, the claims of the Lo patent are not obvious variants of the claims of the present application. When one determination of the two-way analysis does not force a conclusion of obviousness, a double patenting rejection is improper. M.P.E.P. §804.II.B.1.b. Thus, an obviousness-type double patenting rejection cannot be made. In view of the foregoing, Applicants respectfully request that the obviousness-type double patenting rejection over U.S. Patent No. 6,664,056 be withdrawn.

B. U.S. Patent No. 6,258,540

Claims 37-48 are rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-27 of U.S. Patent No. 6,258,540. Applicants traverse this rejection and respectfully request reconsideration because the Office Action has not presented a *prima facie* case of obviousness.

The Office Action on page 10 summarizes the language recited in the claims of the present application and the claims of U.S. Patent No. 6,258,540 and simply concludes, without any analysis, that the conflicting claims are not patentably distinct from one another. The patent laws, however, require more than a mere overlap in claim scope when concluding that particular compounds are obvious variants. As stated by the Federal Circuit:

> The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious. (citation omitted)

In re Baird, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994). As stated in §804 of the M.P.E.P., the analysis employed in an obvious-type double patenting determination parallels the guidelines for analysis of a 35 U.S.C. §103 rejection, which requires analysis of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). No such analysis has been carried out in the Office Action.

As stated above, an obviousness-type double patenting rejection is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. §103. A determination whether one patent application is generic to another patent application is not the appropriate inquiry. The following quotation from *In re Kaplan*, 229 U.S.P.Q. 678 (Fed. Cir. 1986) is instructive:

> By domination we refer ... to that phenomenon ... whereunder one patent has a broad or "generic" claim which "reads on" an invention defined by another narrower or more specific claim in another patent, the former "dominating" the latter because the more narrowly claimed invention cannot be practiced without infringing the broader claim ... In possibly, simpler terms, one patent dominates another if a claim of the first patent reads on a device built or process practiced according to the second patent disclosure. This commonplace situation is not, *per se*, double patenting as the board seems to think. (citations omitted).

Thus, that some of Applicants' claimed methods in the present patent application may also be broader than claims in another patent is not grounds for an obviousness-type double patenting rejection. It is simply a case of one patent dominating another patent. Domination by itself cannot support a double patenting rejection. Thus, the obviousness-type double patenting rejection is misplaced.

To advance prosecution of the present application, however, Applicants will file a Terminal Disclaimer in response to an indication of allowable subject matter. In view of the foregoing, Applicants respectfully request that the obviousness-type double patenting rejection over U.S. Patent No. 6,258,540 be withdrawn.

IV. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to

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contact Applicants' undersigned representative at (215) 665-6914 if there are any questions regarding Applicants' claimed invention.

Respectfully submitted,

Paul K. Legaard, Ph.D.
Registration No. **38,534**

Date: **23 November 2004**

COZEN O'CONNOR P.C.
1900 Market Street
Philadelphia, PA 19103-3508
Telephone: (215) 665-6914
Facsimile: (215) 701-2141